DETAILED OUTLINE OF INSTRUCTION FOR ISO 9000 INSTRUCTOR-BASED TRAINING LESSON 2: OVERVIEW	Course Number: Module: 2 Page 1 of 8
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OVERVIEW	**Slide #2-1**
OVERVIEW OF ISO 9000	**Slide #2-2**
HISTORICAL BACKGROUND **The European Union (EU) originated with the 1957 Treaty of Rome. One intent was to abolish tariffs and quotas among the original six member nations (France, West Germany, Italy, Luxembourg, the Netherlands, and Belgium). The realization of a true European Economic Community (EEC) languished for many years until Europe began to feel economic pressure from Japan and the Pacific Rim countries.** **As part of their effort to thwart economic domination by the Asian countries, renewed effort was undertaken to unite Europe economically. In 1985, the EU Commission presented a program for establishing a single internal market, which included a standard set of requirements for commerce among the nations.** **The ISO 9000 series of standards was several years in the making. (There are those who claim the origins can be traced as far back as 1945 when NATO published its NATO 6-49, and the U.S. Department of Defense published the MIL-Q-9858A and MIL-I-45208A.) The standard was developed in a series of meetings that included U.S. delegates and was first published in 1987 by the International Organization for Standardization (ISO).** **The American National Standards Institute (ANSI) and the American Society for Quality (ASQ) represented the U.S. in meetings during the development of the standards and have jointly published the ANSI/ASQC Q9000 series as the U.S. version of the ISO 9000 series. The first American version was published approximately three months after the publication of the international standard (as the Q90 series). The only changes were those to "Americanize" the British English. There are no actual differences in the requirements. In 1994, several of the documents were revised, and the corresponding American standards were designated ANSI/ASQC Q9000 series.**	**Slide #2-3**

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U.S. MOVE TO ISO 9000 **Any company/organization wishing to do business in the EEC will eventually have to comply with the ISO 9000 standard for their type of operations.** **Recently, NASA, along with several other Government agencies, has accelerated the move to the ISO/Q series. This instructional module is the first among several to assist NASA personnel in becoming familiar with the ISO/Q9000 documentation and philosophy.** **There is also a movement in the U.S. by several large companies to require their suppliers to become registered in the ISO 9000 series. As large companies become ISO certified, they will naturally consider having their suppliers likewise certified, if for no other reason than to make it easier to standardize the auditing of their suppliers.** **The "Big Three" U.S. automobile manufacturers have jointly developed their supplier requirements to coincide with ISO 9000. Their system, QS9000, contains the original 20 elements of ISO 9001, three additional requirements that are designated for all of the "Big Three" (industry-specific requirements), and some supplemental requirements that are specific to each of the "Big Three."** **It is hoped that proof of compliance with the ISO 9000 series will eventually replace most of the customer auditing now experienced by suppliers. There may always be supplemental requirements not covered in ISO 9000 that may necessitate some auditing by customers (auditing beyond third-party audits).**	**Slide #2-4**
NASA POLICIES **In February 1994, the NASA Office of Safety and Mission Assurance (OSMA) issued a directive recommending adoption of ISO 9000 Quality Management Standards. In December 1995, NMI 1270.3 was approved by the NASA Administrator directing compliance of NASA installations and suppliers with ISO 9001. The Administrator issued a directive on November 13, 1996, that requires Marshall Space Flight Center (MSFC), Johnson Space Center (JSC), and Stennis Space Center (SSC) to become ISO 9001 certified by April 1998, with Headquarters and the remaining**	**Slide #2-5**

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NASA POLICIES (CONCLUDED) **Centers certified by September 1999. White Sands Test Facility (WSTF), the first Federal Government facility to be certified, received certification in October 1995.** **NMI 1270.3** **The NMI applies to the NASA HQ, Centers, and suppliers whose processes affect the quality of deliverable products and services. It is optional for the following:** • **Contracts in existence as of December 6, 1995** • **Construction of facilities** • **Institutional support services** • **Off-the-shelf items** • **Department of Defense (DOD) bailed aircraft** • **Non-complex, non-critical, ground-support equipment and commercial items** **The policy requires that NASA and NASA suppliers have a Quality Management System. As a minimum, the system will comply with the current version of "ISO 9000" or "Q9000 Series" and associated documentation. The ISO 9000 Quality System Requirements may be tailored or supplemented to ensure that they include NASA procurement requirements and that unnecessary requirements are not included. Registration/certification is optional, and the procuring organization will establish criteria for compliance.** **ISO 9000 CERTIFICATION DIRECTIVE** **On November 13, 1996, Mr. Goldin issued a directive requiring the Agency to be ISO 9001 third-party certified in key processes by an internationally recognized registrar. This directive applies to all Centers and Headquarters. It is expected that NASA suppliers will also meet this challenge. The timeframes for Agency compliance are as follows:** **April 1998** • **Marshall Space Flight Center** • **Johnson Space Center** • **Stennis Space Center** **September 30, 1999** • **Remaining NASA Centers** • **Headquarters** **The Office of Safety and Mission Assurance will facilitate this effort.**	**Slide #2-5 (concluded)**

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EXPECTED BENEFITS TO NASA **The Agency intends to derive major benefits from the implementation of ISO 9001 and certification. Some of the expected benefits include the following:** • **Improved customer working relationships by realigning NASA's management system to the best commercial practices** • **A "prevention" attitude prevalent throughout the organization, with increased attention to providing improved products or services to customers** • **A management system that is appropriately documented to ensure that consistent approaches are used throughout the Agency** • **Duplication of effort to be minimized with innovative approaches shared across organizational boundaries** • **A better trained and skilled workforce with the resultant efficiency and effectiveness improvements** • **Enhanced ability to compete in the global marketplace** • **Advances in NASA's implementation of numerous Federal acquisition reform initiatives** • **Establishment of NASA as the preeminent Federal agency for quality management**	**Slide #2-6**
RESPONSIBILITIES **In accordance with the ISO 9001 standard and the Administrator's November 13, 1996 Directive, Center Directors will appoint a Management Representative with defined authority for the following:** • **Ensuring that quality system requirements are established, implemented, and maintained** • **Reporting on the performance of the quality system to senior Center management** **The Headquarters Office of Safety and Mission Assurance is responsible for facilitating the ISO 9001 transition and for reporting Agency performance status to Headquarters senior management. Mention that the "Management Representative" will be discussed more fully on a later slide.**	**Slide #2-7**

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OVERVIEW OF THE STANDARDS **Briefly describe the documents listed and explain the difference between the guidance documents and the requirements documents.** **The basic ISO 9000 series is composed of five standards:** • **ISO 9000** • **ISO 9001** • **ISO 9002** • **ISO 9003** • **ISO 9004** **Several other documents support these standards.** **The standards are of two types: guidance standards and conformance or requirements standards.** **ISO 9000 and ISO 9004 are guidance standards. They are descriptive documents, not prescriptive requirements. Companies/organizations do not register to either ISO 9000 or ISO 9004. Instead, they register to one of the conformance standards: ISO 9001, ISO 9002, or ISO 9003. Both ISO 9000 and 9004 have several parts that apply to specific industries or products and/or give guidance in different forms.**	**Slide #2-8**

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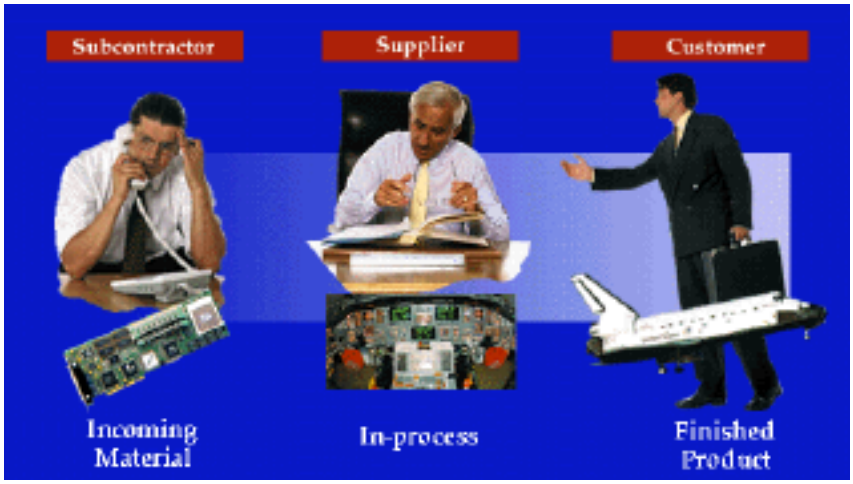
COMMON TERMS **Stress the concept of the supply chain from vendors/subcontractors to suppliers to customers per ISO 9000 definitions.** **Organization** **For the purposes of the ISO standard, an organization is "a company, corporation, firm, enterprise, institution, or part thereof, whether incorporated or not, public or private, that has its own functions and administration." This is a broad definition; the quality system elements in ISO 9000 apply to almost any type of organization.** **Supplier Chain** **The diagram below represents the relationship between the following:** • **The subcontractor** • **The supplier (your organization)** • **Your customer** • **The product**  **The requirements of ISO 9001, ISO 9002, and ISO 9003 are addressed to the supplier. The guidance in ISO 9004-1 addresses the organization.**	**Slide #2-9**

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COMMON TERMS (CONTINUED) **ISO Verbs** **There are two main verbs used throughout the ISO 9000 Standard. The verb *shall* means compliance and is found only in requirements documents. The verb *should* means recommended and is found only in guidance documents.** **Product** **A product is defined as the "result of activities or processes." A product can be tangible, such as assemblies or processed materials, or intangible, such as knowledge or concepts, or a combination of both, such as a service. In clause 4.4 of ISO 9000-1, the standard classifies products into four generic product categories: hardware, software, processed materials, and services.** **Processed Material** **A processed material is "a tangible product generated by transforming raw materials into a desired state."** **Services** **A service is a "result generated by activities at the interface between the supplier and the customer, and by supplier internal activities to meet the customers needs." Note from this definition that there are services provided within an organization. Thus, an organization can have internal suppliers and customers.** **Hardware** **Hardware is a "tangible, discrete product with distinctive form." Thus, hardware normally consists of "manufactured, constructed, or fabricated pieces, parts, and/or assemblies." (ISO 9000-1, 3.1)** **Software** **Software is an "intellectual creation consisting of information expressed through supporting medium." Software can be in the form of "concepts, transactions, or procedures." Some examples are computer programs and the contents of books and procedures. (ISO 9000-1, 3.2)**	**Slide #2-9 (continued)**

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COMMON TERMS (CONCLUDED) **Quality** **Quality is the "totality of characteristics of an entity that bear on its ability to satisfy stated and implied needs." A quality system should address the four facets of quality:** • **Quality due to definition of needs** • **Quality due to product design** • **Quality due to conformance** • **Quality due to product support throughout its lifetime** **Quality System** **A quality system is "the organizational structure, procedures, processes, and resources needed to implement quality management." It "should be as comprehensive as needed to meet the quality objectives."**	**Slide #2-9 (concluded)**